

March 23, 2001

Christine T. Whitman  
EPA Administrator  
1101 USEPA Headquarters  
Ariel Rios Building  
1200 Pennsylvania Avenue, .N.W.  
Washington, DC 20460

Ann M. Veneman  
Secretary of Agriculture  
U. S. Department of Agriculture  
14<sup>th</sup> & Independence Ave., S.W.  
Washington, DC 20250

Bernard Schwetz D.V.M., Ph.D.  
Acting Commissioner  
Food and Drug Administration  
5600 Fishers Lane, Room 14-71  
Rockville, MD 20857

Dear Administrator Whitman, Secretary Veneman and Dr. Schwetz:

This is in follow-up to a letter sent to Mr Robert Lake, Director of Regulation and Policy at FDA, on February 27 and a subsequent meeting on March 1<sup>st</sup> with participants from FDA, CDC, EPA and Aventis. The objective of both the letter and meeting was to emphasize with the Agencies the need for a robust scientific testing paradigm with respect to blood samples taken from individuals alleging adverse reactions to foods allegedly containing Cry9C protein. Aventis strongly believes that a process which ensures scientific rigor in the testing paradigm, as advocated by experts in the field of allergenicity, will avoid raising unnecessary and unfounded concerns with respect to the safety of the US food supply.

Recent press reports indicate that FDA are shortly to begin testing blood samples collected by CDC from individuals alleging to have experienced allergic reactions to corn products supposedly containing StarLink™ corn. The enclosed document outlines the essential points that Aventis has identified associated with any testing protocol for analysis of blood samples to determine the presence of Cry9C specific antibody. The document also identifies a process which determines whether a sample can be regarded as a 'positive' and how to proceed should any 'positive' samples be identified.

As discussed during the March 1<sup>st</sup> meeting, Aventis has commissioned an independent laboratory to develop an ELISA test method for Cry9C specific antibody. This method is now considered as optimized for testing and has been provided to FDA for their use. Aventis has previously supplied Cry9C protein and antibodies to FDA to assist in method development. Aventis remains committed to transfer any technology or protocols to FDA or independent laboratories to move this process forward in a scientifically defensible manner.

Aventis looks forward to working with FDA, CDC and EPA during this process and our scientists remain available to meet with agency personnel.

Sincerely,



John Wichtrich  
Chief Operating Officer